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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,265	09/05/2001	Keiko Yamasaki	2001-1026A	3583

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	9

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,265	YAMASAKI ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' amendment B, filed 02/19/2003; and verified English translation, filed 03/19/2003.

Claims 1-6 are included in the prosecution.

1. The standing rejection:

Claim Rejections - 35 USC § 103

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US 5,725,874 ('874) or US 5,173,302 ('302).

US 874 teaches a percutaneous preparation comprising 0.01 to 20% of a drug; water soluble polymer; water; humectants selected from categories disclosed by applicants, i.e. polyethylene glycol, propylene glycol, butylenes glycol, glycerol, and sorbitol; and cross linking agents (abstract; col.3, lines 28-30, 66-67; col.4, lines 1-2, 14). The dosage form of the preparation can be in the form of reserve patches that have a support (abstract; col.3, line 37; col.4, line 47). The drug to be delivered in the percutaneous preparation includes anti-inflammatory agents selected from diclofenac, ketoprofen, flurbiprofen, flebinac, and indomethacin; and local anesthetic such as lidocain, benzocaine, and procaine (col.2, lines 60-63; col.3, lines 11-12; col.4, line 66 till col.5, line 2).

US '302 teaches a hydrogel formulation useful as adhesive reservoir for transdermal drugs comprises water soluble polymer; cross-linking agent; water; humectants; and at least one active agents including analgesics and anesthetics (abstract; col.1, lines 6-39; col.3, lines 28-31, 54-55; col.4, lines 3, 20-21). The patch has a backing material (col.2, lines 46-67, 64-67).

The references, however, do not teach the combination of both analgesic and anesthetic. It is within the skill in the art to combine two drugs that each one is known to have the same effect in order to have a synergistic effect. US '302 discloses at least one active agent.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver the transdermal patch of any of US '874 or US '302 and include a combination of analgesics and anesthetic in the reservoir, with reasonable expectation of success of the delivered patch to relief pain. Motivation would arise from the general knowledge in the art that analgesics and anesthetics both act in synergism to relief pain.

2. Applicants' arguments:

The main gist of applicants arguments against the rejection of claims 1-6 as being unpatentable over any of US '874 and US '302 is that the it would not have been obvious to one having ordinary skill in the art to predict the synergistic effect of the present invention by combining an analgesic with anesthetic in a transdermal reservoir

to achieve the present invention. No motivation or suggestion in the prior art to modify the teaching of the references to what the inventors have done.

3. Examiner's position:

In response to the above arguments, the examiner position is that the present claims are directed to a product, and all the elements of the product are disclosed by the prior art. The intended use does not impart patentability to product claims. The prior art suggests that at least one drug can be included in the patch (US '302, col.4, line 3), and this would have motivate one of ordinary skill in the art to combine more than one drug in the transdermal patch or reservoir especially if they would provide the same effect, such as an analgesic that relieves pain and an anesthetic that also relieves pain. It is *prima facie* obvious to combine two compositions each of which is known to be useful for the same purpose, such as analgesics and anesthetics, both relief pain. It is obvious to the skilled artisan that combining analgesic to relief pain systemically and anesthetic to relief pain locally would provide more comfort to the patient. The rationale to modify the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art and the reason to modify the reference may often suggest what the applicant has done. In response to applicant's argument that there is no suggestion to modify the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion,

or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, each of the cited references teaches a transdermal administration of the analgesics or anesthetic, and the uses of each drug is known to the skilled artisan, as well as combination of more than one drug used for the same purpose. Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver the transdermal patch of any of US '874 or US '302 and include a combination of analgesics and anesthetic in the reservoir, with reasonable expectation of success of the delivered patch to relief pain.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Isis Ghali
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 16